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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/633,145	08/04/00	KODIRA C	CL000747

EXAMINER	
WEGERT, S	
ART UNIT	**PAPER NUMBER**
1647	8

HM12/1030

CELERA GENOMICS CORP.
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DATE MAILED: 10/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/633,145	Applicant(s) KODIRA ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 20-21, drawn to a receptor protein, classified in class 530, subclass 350+.

II. Claim 3, drawn to an antibody against a receptor protein, classified in class 536, subclass 23.5.

III. Claims 4-5, 8-11 and 22-23, drawn to nucleic acids encoding a polypeptide, complementary nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly, classified in class 435, subclass 69.1+.

IV. Claim 6, drawn to a gene chip, classified in class 435, subclass 69.1.

V. Claim 7, drawn to a transgenic non-human animal, classified in class 800, subclass 8+

VI. Claim 12, drawn to a method of detecting a polypeptide, classification dependent upon structure of recited compound.

VII. Claim 13, drawn to a method of detecting a polynucleotide using a hybridizing oligonucleotide, classified in class 435, subclass 6.

VIII. Claims 14-16, drawn to a method of detecting a modulator or ligand of a polypeptide, classification dependent upon structure of recited compound.

IX. Claim 17, drawn to a ligand and composition, classification dependent on structure of recited compound.

X. Claim 18, drawn to a method of treating a disease by administering a ligand, classification dependent upon structure of recited compound.

XI. Claim 19, drawn to a method of identifying a modulator of gene expression, classification dependent upon structure of recited compound.

Furthermore, applicant is required to elect one sequence from the following:

a) SEQ ID NO: **1**,

b) SEQ ID NO: **2**,

c) SEQ ID NO: **3**, or

d) The **ortholog** of SEQ ID NO: **2** (note: a SEQ ID NO will need to be associated with this sequence if elected for prosecution),

SEQ ID NOs: 1 and 3 are drawn to polynucleotides. SEQ ID NO: 2 and its ortholog are polypeptides.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the

following reasons: Groups I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The protein of Group I can be used other than to make the antibody of Group II, such as used as a probe, or used therapeutically. The nucleic acid of group I can be used in gene therapy as well as in the production of the protein of interest.

Furthermore, Inventive Groups I and III are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is unrelated to inventions IV-V, VII and IX-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group I is neither used in nor produced by any of Inventions IV-V, VII and IX-XI IV-VI.

Invention I is related to invention VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group I can be used to make the antibody of group III.

Invention II is unrelated to Inventions III-V and VII-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group II is neither used in nor produced by any of the methods or products of Groups III-V and VII-XI.

Invention II is related to Invention VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Group II can be for immunoprecipitation of the protein of interest or used therapeutically.

Invention III is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the isolated nucleic acids of Group III can be used in methods that are materially different than the assays that gene chips are used in, such as gene therapy.

Invention III is related to Invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group III can be used for gene therapy or to produce the protein of Invention I.

Invention III is unrelated to Inventions VI, VIII, IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Group III are neither used in nor produced by any of the methods of Groups VI, VIII, IX and X.

Invention III is related to each of Inventions VII and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group III can be used in antisense therapy.

Inventions IV and V are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The gene chip of Invention IV can be used to determine splice variants across various tissues, while the transgene animal of Invention V can be used to study the physiological function of the transporter peptide.

Invention IV is unrelated to Inventions VI, VIII, IX, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different

modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the gene chip of Invention IV is neither used in nor produced by any of the methods of Groups VI, VIII, IX, X and XI.

Inventions IV and VII are related as a process of detecting a compound and the product detected. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05(f)). In the instant case the gene chip can be used to detect polynucleotides in addition to those in Group VII, such as hundreds of possible splice variants as well as related genes. Additionally, the polynucleotide encoding the transporter can be detected by direct *in situ* hybridization.

Invention V is unrelated to Inventions VI-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic animal of Invention V is neither used in nor produced by any of the methods of Groups VI-XI. Furthermore, Inventions VI and IX are independent and distinct, each from the other, because they are products which presumably possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The transgenic animal of Group VI can be used to study phenotypic expression of the gene of interest, while the ligand of the transporter protein can be used to localize the protein.

The methods of Inventions VI-XI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Likewise, Inventions VIII and IX are related as a process of detecting a compound and the product detected. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to find other and materially different product or (2) that the product as claimed can be detected by another and materially different process (MPEP § 806.05(f)). In the instant case a ligand of Group IX could be identified by chemical modification and testing of structurally related compounds. Furthermore, Invention IX is related to Invention X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the ligand of Invention VIII can be used to localize the polypeptide of Group I

Furthermore, each set of sequences (a) – (d) represents a patentably distinct invention. Groups (a) through (d) are independent and distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of Groups (a)-(d) requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventive Groups I through XI, and must additionally elect from Groups (a) - (d). Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the 1026currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

October 30, 2001

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER